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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,216	02/02/2001	James G. Morris	6829/60165 (800189-05)	1182

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EXAMINER	
CHISM, BILLY D	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/776,216	MORRIS ET AL.	
	Examiner	Art Unit	
	B. Dell Chism	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-15,26,27,33 and 37-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *8-15, 26-27, 33 and 46-48* is/are allowed.

6)☒ Claim(s) *5-7,37-45 and 49-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to Applicants' paper filed 01 March 2005. Claims 5-15, 26-27, 33 and 37-64 are pending and under consideration.

Withdrawal of Objections and Rejections

The rejections and/or objections made in the prior office action mailed 15 December 2004, which are not explicitly stated below, in original or modified form are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicants' arguments filed 01 March 2005 will be addressed to the extent that they pertain to the present grounds of rejection.

Claim Rejections - 35 USC § 112

1. (Maintained) Rejection of claims 5-7, 10-15, 37-41 and 52-64 is maintained for the indefinite recitation of the terms "directly available" and/or "indirectly available", wherein the specification is unclear as to what constitutes directly and indirectly available. Applicants argue that the bridging paragraph to pages 4 and 5 is clear as to the definition of "directly" and "indirectly available", however, the paragraph only furthers the indefiniteness. For example, the paragraph states "an effective amount of an amino acid (either the amino acid form, the direct form or the amino acid derived...)". There is alternative language used here that places confusion on whether a free amino acid form is directly available versus the direct form and amino acid derived forms. The paragraph cited by the Applicants makes it appear that "the amino acid form" is different from "the direct form of the amino acid". Again, as in the previous office action, the Applicants' attention is drawn to the specification at page 3, lines 1-2, where the Applicants refer to "pure" or "free" tyrosine, however, there is no mention as to the

availability of the tyrosine. Again at page 11, line 23, applicants use the word "free" in referring to "available" amino acids, however, there is no distinction as to whether free is directly or indirectly available. Claims 57-64 are rejected for depending from indefinite claim 52.

2. (Maintained-in-part/Necessitated by amendment-in-part) Rejection of claims 33, 41-45 and 49-51 and new claims 57-61 is maintained for the indefinite recitation of the term "bioavailable". "Bioavailable" does not necessarily mean "free" or "directly available". Applicants are using different terminology that describes the same product and is not further limiting, i.e., if the composition comprises directly available tyrosine, then the directly available tyrosine would necessarily be bioavailable tyrosine, however, it appears by the claim language that the Applicants are assigning an additional limitation on the directly available tyrosine and that characteristic is inherent to the directly available tyrosine. Thus, it is clear what is meant by bioavailable.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. (Necessitated by Amendment) Claims 52-64 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of maintaining or restoring hair color in cats and dogs, does not reasonably provide enablement for methods of maintaining or restoring hair color in humans or other animals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The instant disclosure fails to meet the enablement requirement for the following reasons:

The nature of the invention: The claimed invention is drawn to a method for maintaining or restoring hair color in animals, comprising supplementing the consumable product containing

particular proportions of tyrosine and/or phenylalanine. The term "animal" encompasses humans, as well as non-mammalian animals that do not have hair.

The state of the prior art and the predictability or lack thereof in the art: The art teaches the use of such methods for the treatment of dogs and cats, however, there is no prior art that teaches methods of using a consumable food supplement as a systemic treatment to maintain or restore hair color in humans. Thus, there is no predictability within the art that would for a nexus between systemic hair color modulation in cats and humans. WO 01/32030 A1 teaches the use of such methods for modulation or maintenance of **fur** for cats, however, there are no teachings of the methods for systemic treatment of human hair color based on consumable food supplements for cats and/or dogs.

The amount of direction or guidance present and the presence or absence of working examples: Given the lack of teachings for predictability found in the art, detailed teachings are required to be present in the disclosure in order for the skilled artisan to be able to systemically maintain or restore hair color in humans by using methods that are for the treatment of cats. These teachings are absent. The teachings found in the present specification are limited to general statements that the method of the invention may be employed to maintain and restore hair color in humans and other animals and working examples describing only how to maintain and/or restore hair color in black cats. There are no teachings and no guidance in the disclosure addressing how to systemically maintain and/or restore hair color in humans or in animals other than black cats. There are no working examples describing either maintenance or restoration of hair color in humans or animals other than black cats.

The breadth of the claims and the quantity of experimentation needed: Because the art does not teach the systemic restoration and maintenance of hair color for humans, it is extremely unpredictable and may actually have a deleterious effect upon both therapeutic efficacy and drug toxicity, and because the disclosure is devoid of any teachings or guidance as to how to overcome the lack of teachings for predictability, it would require undue experimentation by one of skill in the art to be able to practice the claimed invention.

Conclusion

5. Claims 8-15, 26-27, 33 and 46-48 are in allowable form. Claims 5-7, 37-45 and 49-64 stand rejected, with some rejections necessitated by Applicant's amendments and some rejections maintained. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism, whose telephone number is (571) 272-0962. The examiner can normally be reached on M-F 08:30 AM - 5:00 PM. If attempts to reach the

examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, PhD can be reached on (571) 272-0974.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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B. Dell Chism

PATENT EXAMINER

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PATENT EXAMINER